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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/767,663

01/29/2004

Yossi Gross

SC&C-100US

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23122 7590 02/17/2009  
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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

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02/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/767,663	<b>Applicant(s)</b> GROSS ET AL.	
	<b>Examiner</b> Snigdha Maewall	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 51, 70 and 96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51, 70 and 96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/01/08, 11/07/08, 01/26/09</u> .                            | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Receipt of applicant's arguments/Remarks, amended claims and RCE filed on 01/26/09 is acknowledged.

The IDS submitted on 10/01/08, 11/07/08 and 01/26/09 is also acknowledged.

Claims 1-50, 52-69, 71-95 and 97-173 have been cancelled. Claims **51, 70 and 96** are under prosecution.

The rejections/objections not reiterated here have been withdrawn.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/07/08 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 51 recites the limitation "elastic element". The metes and bounds of claim are not defined and thus the claim is indefinite. The claim recites the limitation "substantially" and "improve". The term substantially in claim 51 is a relative term which renders the claim indefinite. The term substantially and improve are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 96 recites the limitation spring like mechanical element, which makes the claim indefinite. Regarding claim 96 the phrase "spring like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

5. Claims 51, 70 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2374149 A Patent to (Thomas et al.) in view of U.S. Patent 6,245,057 to

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Sieben et al. (Sieben) and further in view of U.S. Pg pub 2002/0198470 to Mir A. Imran et al. (Imran) and further in view of Darvish et al. (US Pg Pub 20020183682 A1).

Thomas et al. teaches a swallowable intrabody drug-dispensing capsule comprising a capsule with a sensing module (chemical or electrical), a bio active substance dispenser. The sensing module detects one or more biological conditions within a body. The picture on the front page depicts an embodiment showing drug release into the human digestive system. (abstract). Thomas et al. also disclose a method of drug delivery using the medical device. Thomas et al. further disclose that ingestible medical capsules are known which are capable of sensing a condition such as pH, temperature within the digestive tract and then transmitting that sensed data to receiver to help identify a body location for dispensing a drug (page 3, lines 1-5). The transmitter and receiver are disclosed as wireless communication aids which helps in initiating drug delivery (see page 8, lines 10-30). A suitable power supply includes lithium battery which is non toxic to the body (page 10, lines 10-20). Sensing module can be selected to sense absolute values of pH and also could sense presence of unexpected digestive tract constituent such as blood or cancer cells (see page 17, lines 17-25).

Thomas does not teach driving mechanism comprising electrodes, control units and expansible portion.

Sieben teaches an ingestible capsule (Fig. 3, #1), a drug (Fig. 3, #6), an environmentally-sensitive mechanism (Fig. 3, #9), one or more drug-passage facilitation electrodes (col. 8, claim 12); the control component is adapted to facilitate passage of

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the drug substantially continuously (claim 1, line 57-58); the control component is adapted to facilitate passage of the drug in a pulsatile manner (col. 2, lines 32-33 – it is implied by the disclosure of Sieben that a pulsatile delivery is possible with variation in the detected signal of the pH or similar sensor).

Sieben does not teach a self expansible portion and needle comprising a sharp tip.

Imran teaches the control component adapted to induce local contraction of smooth muscle around the capsule (para. 163, lines 6-12); the velocity-reduction electrodes comprise at least one of the drug-passage facilitation electrodes (Fig. 20, #66, 67). one or more expandable elements (Fig. 20, #76), the expandable elements comprise a portion of the external surface of the capsule (Fig. 20, #76); the expandable elements configured to bring the drug-passage facilitation electrodes into closer contact with a wall of the GI tract (Para. 148, lines 12-16), the expandable elements adapted to increase a diameter of at least a portion of the apparatus by at least 100% (Para. 148, lines 12-16 ). It would have been obvious to optimize the expandable members to expand the necessary amount of contact the lumen of the small intestine to assure the movement stimulations predominantly provide forward movement (Para. 148, lines 24-25), see MPEP 2144.04), at least a portion of the expandable elements comprises a material that dissolves in a controlled manner upon contact with fluids of the GI tract (Para. 148, lines 9-12); the expandable elements (Fig. 20, #76) comprise a plurality of rings coupled together by a plurality of connecting elements (Fig. 20, #76 ).

It would have been obvious to provide a plurality of rings in order to control the electrodes in contact with the lumen of the small intestine to provide desired forward or

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slowed peristalsis, see MPEP 2144.04 VI), the rings configured to define a longitudinal opening (Fig. 20) there through having a diameter equal to at least 50% of a diameter of a lumen of the GI tract (Para. 148, lines 12-16 – it would have been obvious to optimize the expandable members to expand the necessary amount of contact the lumen of the small intestine to assure the movement stimulations predominantly provide forward movement (Para. 148, lines 24-25), see MPEP 2144.04); the rings are bent such that the lumen is generally circular in cross-section (para. 148, lines 2-4 – Imran teaches a loop, which could be circular as would have been recognized by one of ordinary skill in the art and still provide the same function of supporting the electrodes to better contact and control the contractions of the smooth muscle of the intestinal walls), and the diameter of the opening is equal to at least 75% of the diameter of a lumen of the GI tract (Para. 148, lines 12-16 – it would have been obvious to optimize the expandable members to expand the necessary amount of contact the lumen of the small intestine to assure the movement stimulations predominantly provide forward movement (Para. 148, lines 24-25), see MPEP 2144.04).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the velocity-reduction element of Imran in the ingestible device of Sieben in order to treat absent, weak, sporadic or non-optimal smooth muscle contractions as explicitly taught by Imran (para. 34, lines 1-5).

Darvish et. al. teaches drug delivery device comprising electrode, power source, controller, electrifying the electrode and to affect transport of a molecule in a desired manner to desired tissue or vasculature (see abstract). In one of the embodiments, the

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reference discloses that the invention relates to treating coronary blood vessels or other blood vessels that are near or inside the heart using electrically mediated molecule transport (see paragraph [0017]). The apparatus comprises wireless programming (paragraph [0026], control connection, electrode and sensors (figure 2. The reference teaches in some cases the electrodes can double (see paragraph [0192]). The reference teaches under exemplary pulse properties, variation of iontophoresis and various volts and current that can be varied (see paragraph [0069]).

It would have been obvious to one of ordinary skill in the art the time the instant invention was made to utilize sensors and wireless transmitters with the ingestible device of Sieben et al. One would have been motivated to do so with a reasonable expectation of success because the reference teaches transport of a molecule in a desired manner to desired tissue or vasculature (see abstract). It would have been further obvious to vary frequency and pulses and time periods in order to obtain optimum results since Sieben and Darvish, both teach the drug delivery mechanism /comprising ,control component, electrode ,sensor and wireless transmitter and receivers in drug delivery device apparatus.

### ***Response to Arguments***

6. Applicant's arguments with respect to claim 51, 70 and 96 have been considered but are moot in view of the new ground(s) of rejection.



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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore /

Primary Examiner, Art Unit 1612